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Criteria for the Collection of Useful Respirator Performance Data in the Workplace

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Abstract

Workplace protection factors (WPFs) are intended to measure the ability of a respiratory protective device (RPD) to reduce contaminant exposure when used in the context of an effective respiratory protection program. In 1992, members of the American Industrial Hygiene Association Respiratory Protection Committee (RPC) published a review of important issues and considerations for measuring respirator performance in the workplace. The RPC recognized that respirator testing in workplaces can have a variety of objectives and endpoints, and that not all workplace measurements are WPFs. That paper addressed concerns in the general categories of 1) study objectives; 2) site selection; 3) subject selection and preparation; 4) sampling and analytical methods; and 5) data analysis. No specific protocol for measuring WPFs was recommended by the RPC, and attempts to reach a U.S. consensus on a WPF protocol since 1992 have not succeeded. Numerous studies have implemented the principles for WPF measurement described in the RPC paper. Modifications to the original recommendations have been made to reflect the current state of the art. This article describes what has been learned in recent years in each of the five categories identified in the 1992 discussion. Because of the wide variety of workplaces and work activities, contaminants and respiratory protective devices, a strict protocol is not appropriate for collecting WPF data. Rather, the minimum requirements for the collection and presentation of meaningful respirator performance data in the workplace are described. Understanding of these principles will permit useful RPD performance data to be generated.

Keywords

respirator; workplace protection factor; respirator performance; WPF

INTRODUCTION

The critical purpose of a respiratory protective device (RPD) is to reduce wearers' inhalation of air contaminants from concentrations considered too high to those considered acceptable. Because requirements for RPD certification are based on laboratory tests using conditions

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that are significantly different from workplace environments, testing RPD in the workplace represents a way to verify performance and assure wearer protection. In addition, data from workplace studies are sometimes used in setting assigned protection factors (APFs). The Occupational Safety and Health Administration (OSHA) defines APF as "… the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program…" [(1)] Statistically, where sufficient data exist, APFs represent work-place protection factor (WPF) values that will be met or exceeded by most wearers during at least 95% of their wearing periods.

To be a useful measure of RPD performance or for use in setting APFs, WPF measurements must be collected in a manner that accurately represents the protective capability of the device. The data should be presented in a manner that allows data analyses by interested third parties. Because of the diversity of workplaces and work activities, contaminants and respiratory protective devices, a strict protocol is not appropriate for collecting WPF data. This article reviews essential criteria for collecting meaningful RPD performance information in workplaces, and identifies minimum requirements for presentation of the data in a useful manner. It includes information to address the overall issue of respirator performance measurement, which the American Industrial Hygiene Association Respiratory Protection Committee (RPC) identified as a research priority in 2009.[(2)] The listing of research priorities was subsequently forwarded to the National Institute of Occupational Safety and Health (NIOSH) for consideration. This article is a result of collaborations between NIOSH and members of the RPC to address this recommended priority.

BACKGROUND

It is important to recognize two key principles before the collection or analysis of workplace RPD performance data:

- All RPD used in the United States must be selected, maintained, and used in the context of a comprehensive respiratory protection program. The elements of a minimally acceptable program have been codified since 1971 for most U.S. employers in the OSHA regulation, *29 CFR* 1910.134 [(1)]; other regulatory agencies have similar requirements.[(3–5)] Because only NIOSH-certified respirators are permitted by these regulations, only respirators that have passed all certification test requirements and received certification are candidates for WPF study. APFs do not apply to RPD used in the absence of a fully compliant RP program; less than the expected level of protection is anticipated in these situations.[(1,6)]
- While all workplace RPD performance testing involves measuring the air contaminant concentration outside (C_o) and inside the device (C_i), not all measurement data collected reflect the protective capabilities of the device under evaluation. For example, wearer protection can be compromised if RPD are not properly selected and used, poorly maintained, or not worn for portions of the exposure period. In such cases, poor protection is due to deficiencies in the organization's respiratory protection program rather than an inherent deficiency of

the device. To clarify this important distinction, the RPC developed, and subsequently updated, three definitions relevant to workplace RPD testing [7,8]:

1. Workplace Protection Factor (WPF)

A measure of the protection provided in the workplace, under the conditions of that workplace, by a properly selected, fit-tested, and functioning respirator while it is correctly worn and used. WPF is a direct measurement of respirator performance capabilities in a specific work environment. It represents the workplace contaminant concentration outside the respirator (C_o) divided by the contaminant concentration inside the respirator (C_i). C_o and C_i are measured simultaneously only while the respirator is properly worn and used during normal work activities. C_i measurements made using respirators that are poorly maintained, improperly used, or not worn during the entire exposure period are inappropriate for WPF determination (see definitions for Effective Protection Factor and Program Protection Factor).

2. Effective Protection Factor (EPF)

A measure of the protection provided by a properly selected, fit-tested, and functioning respirator when it is worn for only some fraction of the total exposure period in the workplace. It is the ratio of the contaminant concentration outside the respirator to that in the air actually inhaled. It is determined by sampling outside the respirator and in the breathing zone during the total exposure period, regardless of whether the respirator is being worn. While the respirator is worn, breathing zone sampling is done from within the respirator. EPF is strongly influenced by non-wear time, regardless of the respirator's WPF. EPF may also be estimated by correcting appropriately measured workplace protection factors (WPF) for the time that the respirator is not worn during the exposure period using the following formula. It can be validly applied only if the air contaminant concentration is relatively constant over the exposure period.

$$\mathrm{EPF}=\frac{\mathrm{T_S}}{\frac{\mathrm{T_W}}{\mathrm{WPF}}+\mathrm{T_{nw}}} \quad (1)$$

Where:

T_s = Shift or exposure duration (hr).

T_w = Number of hr respirator is worn.

T_{nw} = Number of hr that respirator is not worn.

3. Program Protection Factor (PPF)

An estimate of the respiratory protection provided to a worker in the context of a specific respirator program. It is defined as the contaminant concentration that the user would inhale if the respirator were not worn (C_o) divided by the contaminant concentration inside the respirator as it is actually used (C_i). C_i may be estimated from biological monitoring as the airborne concentration expected to produce the measured biological index. PPF is an

estimate of the effectiveness of the complete respirator program rather than the performance capabilities of the respirator itself. It is affected by such factors as the following:

- **a.** Wearers' activities
- **b.** User training and motivation
- **c.** Proper respirator selection, maintenance, and storage
- **d.** User training and fit-testing
- **e.** Facial hair or other conditions that interfere with proper fit, and
- **f.** Supervision, administration, and monitoring of the program.

If any of these or other program elements are deficient, the program protection factor will be adversely affected. (Authors' note: Biological monitoring is not appropriate for estimating PPF for contaminants with the risk of skin absorption ingestion, or if there is a substantial background level in body fluids due to non-occupational sources).

Although workplace respirator testing has been done in the United States for more than 35 years,[9–11] these definitions to properly categorize the test results were not formally developed until 1985.[7] However, the difference between RPD capabilities, i.e., WPF and EPF, were recognized by some early investigators.[10] Proper use of the terms above is necessary not only to understand workplace measurements but, more importantly, identify what steps are necessary to improve wearer protection: changing to a higher-performing RPD will likely not improve protection in a poor RPD program.

A paper by Johnston et al.[12] reviewed the "state of the art" in workplace RPD testing circa 1990 and represented the first attempt to offer guidance on how workplace data should be collected and analyzed. The authors identified five considerations for workplace RPD performance testing:

- Study objectives
- Site selection
- Subject selection and preparation
- Sampling and analytical methods
- Data analysis.

Johnston et al. suggested that reaching consensus on these issues could eventually lead to standardized workplace RPD test protocols. They also listed 10 basic rules specific to collecting WPF data (Table I). A number of WPF studies published since 1992 have applied the principles discussed by the authors and used all or most of their recommendations.[13–24] These studies have revealed both the utility and limitations of the information and guidance provided in the Johnston et al. paper. The knowledge gained from those studies is the basis of this article, which is intended to supplement the earlier work by Johnston et al. Issues not addressed in this article default to the discussion and recommendations of the earlier work. In other cases, new recommendations are made to further improve the reliability of workplace RPD performance testing.

METHODS

Papers with apparent relevance to workplace testing of RPD were drawn from the peer-reviewed literature published over the last 40 years. Most papers reviewed came from one of three journals with occupational safety and health and/or respiratory protection emphasis:

1. *Journal of Occupational and Environmental Hygiene* and its predecessors published by the American Industrial Hygiene Association: *AIHA Journal, AIHAJ, and American Industrial Hygiene Association Journal.* The database further included *Applied Industrial and Environmental Hygiene and Applied Industrial Hygiene*, both published by the American Conference of Governmental Industrial Hygienists (ACGIH®).
2. *The Annals of Occupational Hygiene*, published by the British Occupational Hygiene Society.
3. *Journal of the International Society for Respiratory Protection*.

The search resulted in 48 studies of RPD performance in work environments. The total includes studies whose measurements were (or should have been) called EPFs or PPFs, as well as true WPF studies. Seventeen of the studies were published prior to 1992 and 31 were published in 1992 or later. Some of the studies conducted prior to 1992 followed protocols similar to the procedures recommended by Johnson et al., while several published after 1992 used different methods. Studies that were not cited in the text of this article are included as an appendix.

STUDY OBJECTIVES

Johnston et al. noted that not all workplace RPD evaluations are intended to collect WPF data, and that clear statement of the study objectives is necessary for proper interpretation of the results. Consistent with the RPD performance terms defined above, the procedures for collecting data differ with the objectives of the study. For example, a study might be done to test the hypothesis that RPD in use reduce wearer exposures (C_i) from ambient concentrations (C_o) above an occupational exposure limit (OEL) to an acceptable concentration inside the RPD. These data could be collected using EPF-, PPF-, or WPF-style protocols, although ethical considerations preclude EPF or PPF protocols if adverse effects from acute, potentially high overexposure are possible. Each protocol could demonstrate acceptable C_i exposures, but only the WPF procedure would be a valid indicator of RPD performance. Should the hypothesis be disproven in an EPF or PPF study, the overexposure could be due to any combination of underperforming RPD, lack of wear time, or other RP program deficiencies. Appropriate corrective action would not be apparent.

Other objectives for workplace testing of RPD include verification of a current APF for a particular RPD, or to estimate an entire distribution of workplace performance for a device. In either case only WPF protocols are acceptable. As will be shown later, the requirements for workplace C_o differ for these two objectives.

SITE SELECTION, SUBJECT SELECTION AND PREPARATION, SAMPLING AND ANALYTICAL METHODS

Johnston et al. addressed the concerns of site selection, subject selection and preparation, and sampling and analytical methods individually. However, each is related to and may be impacted by the others; they should be considered simultaneously.

Site Selection

A comprehensive listing of practical considerations for choosing a worksite for RPD testing is given in Johnston et al. In large part they are the concerns relevant to any industrial hygiene sampling program. Additional issues specific to RPD testing included types of RPD in use, completeness of the RP program, and compliance with fit-testing and training requirements. Johnston et al. reasoned that a complete, standing RP program was critical to the conduct of a WPF or EPF study. Emphasis was placed on potential subjects' past training, fit-testing, and experience with the RPD to be tested. They believed that the level of experience could influence the outcome of the performance measurements. Although not stated, this implies that training and fit-testing alone are not sufficient to assure adequate performance, and that some unspecified amount of experience is necessary to achieve protection.

However, limited data suggest that this concern is unfounded. Janssen et al.[20] collected WPF measurements on 18 workers that included two newly hired subjects trained and fit-tested by their employer during the study. All the WPF values were much higher than the APF for the full facepiece respirator tested, and only one of 52 C_i samples showed detectable lead contamination. In another study, workers who were inexperienced with the filtering facepiece respirator under investigation achieved WPF values in excess of the APF of 10 for the RPD.[21] In both studies the workers were continually observed to assure the RPD was continuously and properly worn, but there was no other intervention. It appears that initial training and fit-testing are effective and along with continuous, proper use (all of which are necessary program elements) are sufficient to assure representative RPD performance for workplace testing. Training and fit-testing provided by the employer and by the study investigators appear to have indistinguishable results.[13,20,21,24] Therefore, lack of a *standing* RP program and/or inexperienced RPD users should not be viewed as an obstacle to collecting acceptable WPF or EPF data. Nonetheless, investigators are obligated to discuss the need for an ongoing, effective RP program with the employer.

Subject Selection and Preparation

Beyond training, fit-testing, and proper RPD use, additional subject selection and preparation criteria for WPF measurements are pragmatic. Prospective subjects must be willing and able to wear multiple pieces of sampling equipment and safely do their jobs, comfortable with being observed continuously during test periods, and agree not to remove the RPD until sampling devices are stopped.

Sampling and Analytical Methods

The single most important consideration in site selection is the presence of enough of an air contaminant to allow the desired C_o/C_i ratios to be measured. (Note that while it is actually the gross amount of C_o and C_i contaminant that can be collected that is important, e.g., mass, number of particles, these will hereafter be expressed as C_o and C_i for convenience). Since all RPD performance measurements are simply ratios, the contaminant need not have an OEL.

The necessary C_o is dependent on the study objective and the analytical methods available for that contaminant, as well as the analytical limit(s) of quantification (LOQ). (Note: The paper of Johnston et al. and many subsequent WPF studies used the term “detection limit” in lieu of LOQ. The latter is the more correct term, in that it indicates the lowest level at which contaminant can be measured with a known degree of confidence. It will be used throughout this article except when quoting Johnston et al.). For example, if the study objective is to demonstrate that RPD wearer C_i exposures are below an OEL, the analytical method need only be sensitive enough to detect concentrations at or below that value. This could be demonstrated with WPF, EPF, or PPF measurements. If the objective is to demonstrate that the existing APF for a device is adequate (e.g., 10 for a half facepiece), only WPF protocols are appropriate. In addition, with this objective the ratio of C_o to the minimum quantifiable C_i must be at least equal to the APF to measure that value. For other types of respirators with higher APFs, higher ratios equivalent to the device APF are needed. Critically, when C_o is near the minimum required to measure the APF, statistical analysis of these data must be done with caution, since the full distribution of C_o/C_i ratios may not be known.

Much higher C_o and a very sensitive analytical method are necessary to measure the full distribution of WPFs. This is critical because individual WPF measurements frequently exceed half and full facepiece APFs by many times.[13–16,18–22,24] Insufficient C_o relative to the C_i LOQ can make the higher WPFs appear artificially low if, for example, the C_i LOQ (or some fraction of it) is substituted for C_i samples below that value to calculate WPFs. Very high WPF measurements are not unexpected. Quantitative fit factors (i.e., laboratory measurements of C_o:C_i ratios using specific procedures) of several hundred to several thousand are routinely measured with half facepieces,[25] and there is no inherent reason the fundamental fit of the facepiece should be poorer in a workplace than in a fit-testing environment. In this context, fundamental fit refers to the basic relationship established between the facepiece and the wearer’s face when a respirator is donned.[26] It has been suggested that vigorous work activities causing momentary breach of the faceseal may account for a significant portion of the C_i measured in WPF studies.[13,14,20–22,24] Some evidence also suggests that work activities more closely resembling fit-test exercises may be associated with higher WPFs.[22,24]

Johnston et al. suggested the following for minimum C_o acceptance criterion, although the reason given was to account for poor analytical confidence at or near the analytical detection limit. It also appears to be a “reminder” that industrial hygiene samples must be corrected for blank contamination, which is especially important for samples near the LOQ:

$$\text{Outside Sample Analyte Weight} = 10 \times \text{APF} \times \text{Mean Field Blank Analyte Mass}$$

This criterion is more broadly (and simply) stated as:

$$\text{Minimum Outside Sample Quantity} = 10 \times \text{APF} \times C_i \text{ Analytical LOQ}$$
$$(\text{with Quantity and LOQ expressed in the same units, e. g. , mass, number of particles})$$

This is true because industrial hygiene sampling and laboratory analysis procedures routinely require the use of blank samples, and blank correction is a necessary part of data interpretation. The revised criterion is advantageous in that it does not restrict potential WPF worksites to those with contaminants whose presence is measured in mass. For example, particles measured by count or by surface area are potential challenge agents. Unlike the original criterion, it is also useful in site selection: mean field blank values are not known until after samples are collected. Additionally, the revised criterion is applicable when using direct reading instruments such as particle counters that do not require blank samples. In these situations the original criterion cannot be applied.

Subsequent studies have suggested higher minimum outside contaminant levels to allow more of the WPF distribution, if present, to be measured:[24]

$$\text{Minimum Outside Sample Quantity} = 100 \times \text{APF} \times C_i \text{ Anaytical LOQ}$$

Still higher levels are desirable to confidently measure the full WPF distribution. However, even the “100X” criterion is hard to satisfy for RPD with high APFs, e.g., supplied air hoods, because exceptionally high contaminant levels are necessary. It may be difficult or impossible to measure the upper end of the WPF distribution for these devices. However, in some cases longer sampling times and/or higher flow rates can reduce this problem.

Johnston et al. observed that workplace sample rates of 1–2 L/min were commonly used, “to avoid significant pressure changes inside the respirator facepiece.”[12, p.708] Neither the flow rate above which these pressure changes might be expected, nor what pressure change was considered “significant,” was specified. Subsequent studies have used flow rates up to 10 L/min without a discernible effect on WPFs.[27–29] Pressure drop of current NIOSH-certified U.S. particulate respirator filters is low, typically on the order of 10 – 20 mm water for N95 and P100 classes, respectively, at a flow rate of 85 L/min.[30] Because pressure drop decreases directly with decreased flow rate, the measurements at 10 L/min will be significantly lower than these values.

It has also been shown that increased negative pressure within a facepiece does not increase faceseal leakage in properly fitted respirators,[31,32] so flow rates up to 10 L/min are not a concern for that reason. Furthermore, flow rates ≤10 L/min are a fraction of both inhalation flow[33] and the flow rate at which particle filters are currently tested for NIOSH certification in the United States.[34] Published data demonstrate they will not significantly increase penetration for current NIOSH-certified U.S. filters or their equivalents.[35,36]

Nonetheless, if there is doubt or if significantly higher flow rates are considered, penetration measurements should be made using particle sizes representative of those found in the workplace. Potential for C_i sample bias induced by the higher flow rate must also be investigated. If either is found, a lower flow rate should be considered or corrections made to C_i measurements, as appropriate. Additionally, sample flow rates for gas phase contaminants may be limited by the sample collection media, e.g., the flow rate must allow adequate residence time for activated charcoal and other solid sorbents.

Johnston et al. noted that analytical methods must be extremely sensitive and specific to detect very small amounts of C_i contamination. This also requires that C_i samples be handled carefully to avoid contamination that could add a significant negative bias to WPF values. As noted earlier, blank correction of C_i samples collected on media such as filters may be necessary. Because people are known to generate and exhale aerosols from the respiratory tract,[37,38] C_i measurements made with size-selective particle counters should also be appropriately corrected. This necessitates the characterization of each test subject's respiratory aerosol generation across the particle size ranges to be measured. It is also critical that subjects refrain from smoking or workplace particle exposure for at least 1 hr before characterization or workplace sampling.

Similar precautions apply when gas or vapor contaminants are considered as challenge agents for workplace testing. The period of time that test subjects might exhale the contaminant from previous inhalation or skin absorption of the contaminant of interest must be determined, and an appropriate post-exposure interval determined to allow the exhaled breath to clear. In other cases the exhaled breath concentration may be shown to reach an equilibrium concentration, and adjustments made to C_i to correct for this "background" contaminant exhaled by test subjects.[39,40] Non-specific analytical methods, e.g., gravimetric, must be used with great caution since C_i can be biased by sweat, sputum, and other worker-generated materials.[12,14]

Most WFP studies published in the United States have used Co and Ci measurements "as reported" to calculate WPFs.[13–24, 28,29] Nonetheless, some investigators have suggested positive corrections to C_i measurements to account for sample losses such as retention of particles in the respiratory tract, respirator dead space, and loss of particles on cassette walls.[27,41] While theoretically correct, some of the suggested corrections rely on models using assumptions that may be incorrect in the workplace. Lung retention models require assumptions concerning worker size, airway structure, and respiration rate, and also require knowledge of the particle size distribution *inside the RPD*. When C_i aerosols are collected on filters, there is no practical way to measure their size distribution, which in most cases will differ from the ambient size distribution.[42,43]

Laboratory studies using faceseal leaks of fixed diameter, length, and shape have shown that particles of different sizes and shapes penetrate those leaks with disparate efficiencies.[42, 44–48] Hinds and Bellin developed a model to estimate penetration of workplace aerosols through filters and faceseal leaks as a function of particle size, but its leak size estimate assumes a constant leak based on the worker's fit factor measured during quantitative fit-testing (QNFT).[49] Both QNFT[50,51] and WPF[13,21,22,24] studies conducted

after the model was developed have shown that the "fixed leak" assumption is likely incorrect for individuals wearing RPD. Several WPF studies have found particles >10 μm on C_i filters; their presence has been attributed to relatively large, dynamic leaks that are not expected to be particle size selective.[13,21,22,24] It is likely these dynamic leaks can exist either in conjunction with, or in the absence of. fixed leaks.[21]

It has also been demonstrated that streamlining and incomplete mixing of air in a tight-fitting facepiece can significantly affect the amount of material collected by a C_i sample in both QNFT and WPF measurement. That is, the C_i sample can indicate a greater or lesser contaminant concentration than the RPD wearer actually inhales.[52,53] This phenomenon adds uncertainty to the correction of C_i for lung retention. However, streamlining effects were determined using single or combinations of fixed leaks. It is not known how the presence of dynamic faceseal leakage affects the mixing of air within the RPD, so its effect on the C_i is also unknown. Location of the C_i sample probe specified by Johnston et al. remains the preferred method to minimize potential biases due to in-facepiece streamlining. In summary, correction of C_i samples for respiratory tract deposition must be done with considerable caution and full understanding and disclosure of the uncertainties that can affect the estimate. It may be wise to limit this correction to studies in which the C_i particle size distribution is actually measured, as is possible in the case of samples collected with appropriate particle counting instruments.

To investigate the need to correct C_i samples for cassette wall losses, Myers et al.[13] measured the losses for zinc in a WPF study and found the them to be very small (~6% of the C_i) mass. The amount of mass on the cassette walls did not correlate with mass on the C_i filter ($R^2 = 0.001$). Nonetheless, more recent studies of cassette wall losses for routine workplace samples, i.e., the equivalent of C_o samples in workplace studies, have lead OSHA to conclude "… wall deposits can often be a large and inconsistent fraction of the total sample."[54, p. 734] The OSHA authors also noted that it is not possible to apply a correction factor to account for wall losses. As a result, OSHA's laboratory now requires that internal cassette walls for all metal samples be wiped, and any mass collected included in the analytical result. The *NIOSH Manual of Analytical Methods* also suggests this practice.[55] Thus, future WPF studies using standard filter cassettes should include wiping the internal walls of both C_o and C_i samples. Any contaminant found on cassette walls should be included in the respective C_o and C_i masses. Because the amount of material lost to cassette walls is highly variable, it is not possible to determine if results of previous studies might have been affected.

Importantly, when direct reading instruments, airborne biological contaminant sampling, or other non-standard industrial hygiene laboratory analytical methods are used, sampling and analytical errors, as well as quantification limits, must be determined and stated by investigators.

Data Presentation and Analysis

Consensus does not yet exist on the optimal method for statistical analysis of RPD workplace performance measurements, and this article does not advocate a specific statistical method. However, it can be said that most WPF studies published in the United

States have used the lower 5th percentile point estimate of a log-normal WPF distribution as a plausible and conservative value for an APF for the class of device under evaluation.[14–16,18–22,24,27–29] OSHA also used this method to establish several legally mandated APFs for several types of RPD.[56]

Complete presentation and understanding of the sampling data are critical to any statistical analysis. Johnston et al. identified criteria for excluding data from the analysis, which are to be established prior to collecting workplace performance measurements. These criteria include sampling pump failure, C_i sample contamination, e.g., removal of the RPD during sampling, low C_o, and less than continuous subject observation. Data presentation should include, at a minimum, sample duration, C_o and C_i results and WPF estimate for *every* valid sample pair to facilitate understanding and analyses by third parties. Because of the uncertainties associated with sampling and analysis and, in particular, in-facepiece sampling, in most cases WPFs should be rounded down to no more than two significant figures. The use of decimal places overstates the precision of workplace RPD measurements and is *never* appropriate in the presentation of WPFs.

Because RPD performance in WPF studies may be better than reflected by their APF, it is not uncommon for results to include a significant number of C_i samples with no detectable contamination. In such instances the treatment of these samples in the data analysis must be carefully considered and clearly explained. While substitution of an analytical LOQ or a fraction thereof has been common practice, random effects, nonparametric, and censoring regression models have also been used.[29,57,58] When most or all C_i samples in a study are below the quantification limit, as is often the case in studies of high-performing respirators,[17,20,23,24] meaningful WPF distributions cannot be calculated. In these cases, reporting WPFs as values “greater than” a minimum value calculated using the quantification limit as the C_i mass (for example) may be most appropriate: This process avoids bias and error introduced by assumptions regarding the C_i distribution or the expected level of performance (APF) for the device.

Other data interpretation considerations are relatively new and must also be resolved. Most workplace RPD performance measurements to date, including WPFs, have been collected as integrated samples over periods of approximately 1 to 2 hr, using traditional industrial hygiene sampling and laboratory analytical methods.[13–24] In at least one study, work shift time-weighted average (TWA) WPFs were calculated.[21] These practices were clearly appropriate for materials with OELs expressed as 8-hr TWAs. However, in recent years several investigators have collected workplace RPD performance measurements using direct reading instruments (e.g., particle counters) and biological sampling methods.[27–29] In these studies, samples are usually collected only for some fraction of a work period, e.g., the first and last 15 min of a 60-min work period. This raises the traditional industrial hygiene issue of assuring such samples are representative of the “true” exposures and WPFs. Secondly, a significant departure from traditional workplace testing in these studies is the calculation of WPFs for specific particle size fractions and for specific organisms, as well as integrated WPFs for all particle sizes. At this time it is not known how these values should be interpreted or compared with WPFs collected using more traditional methods, nor is their industrial hygiene significance clear.

ADDITIONAL RESEARCH NEEDS

To date, most workplace studies have measured RPD performance against particulate contaminants.[13–24] It has been assumed (as reflected by current APFs) that RPD performance is equivalent for gas and vapor RPD of the same class. More workplace studies with gas-phase contaminants are necessary to confirm or refute this assumption. As noted earlier, these contaminants may require development of reliable methods to quantify and correct for skin absorption and possible release of contaminant in subjects' exhaled breath. In addition, the need for optimal in-facepiece sampling and analytical methods for gas-phase contaminants was identified by Johnston et al. These issues are not yet fully resolved.

Because worker exposures and use of RPD have evolved to include materials such as engineered nanoparticles and infectious bioaerosols for which exposure conditions and metrics are largely unknown, these are critical issues in RPD performance measurement. It is likely that airborne concentrations will be low relative to traditional industrial contaminants.[59–61] Thus, existing sampling and analytical methods may require modification and validation at extremely low quantities. Development and validation of small, field-serviceable instruments to measure C_o:C_i ratios for these contaminants will likely be necessary. Sampling methods for bioaerosols must be able to differentiate between infectious and non-infectious particles to gain the acceptance of WPF measurements by those outside the industrial hygiene community.

Finally, as RPD performance improves and exposure limits are lowered, higher flow rates for in-facepiece samples will become a necessity. Flow rates above 10 L/min should be fully explored to determine potential effects on inlet probe performance and in-facepiece sample bias. It may also be possible to determine a maximum acceptable sampling rate for each class of RPD.

CONCLUSION

Workplace RPD testing can provide valuable information on worker exposures, RPD performance, and RP program efficacy. Knowledge gained over the past 20 years has refined and clarified measurement techniques and understanding of RPD performance. Because the use of RPD, work-places, and exposures are variable and evolving, a restrictive protocol for WPF measurements is not appropriate. A full understanding of the principles underlying the data collection requirements allows flexibility and adaptability of methods for RPD performance assessment.

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APPENDIX

Supplemental References

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TABLE I

Johnston et al. Basic Rules for Workplace RPD Studies

1	Prior to sample analyses, invalidate sample sets affected by sampling problems, such as leaky probes, loose sampling devices, loose hoses, malfunctioning pumps, removal of the respirator while pumps were running, or other observations that indicate the protocol was not met.
2	After sample analyses, reject sample sets with insufficient inside or outside sample loading or unacceptable analytical precision.
3	Use the mean value of field blanks to correct inside and outside sample loadings.
4	Use corrected sample loadings to calculate concentrations and protection factors. Be sure proper terminology is used (i.e., WPF as opposed to EPF, PPF, and so forth).
5	Consider whether corrections are desirable for lung retention. Determining factors may include sampling strategy used and type of contaminant.
6	Calculate appropriate measures of distribution, such as geometric means, geometric standard deviations, and fifth percentiles.
7	Identify potential outliers. Investigate reasons. Retain or reject data points in question.
8	Examine data to determine if protection factors generated are independent of outside sample loading. If not, re-evaluate amount of mass collected.
9	Test for differences among respirators, test subjects, observers, operations, and days as appropriate for the study design.
10	Define any problems encountered with data analysis that may make the results unsuitable for defining protection factors. Be sure to describe clearly conditions for which the study may be relevant. Avoid over-interpretation of results.

Source: (12)